

**REMARKS**

Claims 1-31 are pending in the present application. Claims 19-23 were previously withdrawn from consideration as drawn to a non-elected invention. By virtue of this response, claims 1-3 have been cancelled, without prejudice; and claims 4-5, 12, 25-28, and 30-31 have been amended. Accordingly, claims 4-18 and 24-31 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Applicants reserve the right to prosecute cancelled or amended subject matter in related patent applications.

Applicants thank the Examiner for the indication at page 9 that claims 6-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten. Applicants point out that claims 6-7 are not dependent upon a base claim, and therefore, Applicants believe should be considered in shape for allowance.

Applicants thank the Examiner for returning the initialed IDSs.

**Claim Rejections Under 35 U.S.C. 112, second paragraph**

Claim 5 stands rejected under 35 U.S.C. 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants traverse this rejection of claims. Applicants submit that claim 5 is in compliance with Section 112, second paragraph. Without acquiescing to this rejection and solely in an effort to expedite prosecution, Applicants have amended claim 5 to recite, in part, that “said vector contains a minimal promoter in place of the p5 promoter, wherein the minimal promoter contains a TATA box as its only regulatory element”, thereby obviating the Examiner’s rejection. Applicants request withdrawal of this rejection of claim 5.

***Claim Rejections Under 35 U.S.C. § 102(b)***

Claims 1-4 and 25-30 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Natsoulis (US 5,622,856).

Applicants traverse this rejection of claims. Applicants point out that Natsoulis state at col. 3, lines 32-36 that the P5 promoter region has been moved from its normal upstream position, and at lines 45-52 that the p5 promoter is situated in a site other than its normal upstream position. Applicants believe that Natsoulis does not identically disclose or describe, within the meaning of 102, the claimed invention. Without acquiescing to the rejection and solely in an effort to expedite prosecution, Applicants have cancelled claims 1-3, without prejudice, and have amended claims 4-5, 12, 25-28, and 30-31, thereby obviating this rejection. Applicants request withdrawal of this rejection.

***Claim Rejections Under 35 U.S.C. § 103(a)***

A. Claims 1-4, 8-10, 12, 14-18 and 24-30 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Salvetti et al (US 6,509,150) in view of Mountz and Zhang (US 5,589,377).

Applicants traverse this rejection of claims. Applicants do not agree or concede that a *prima facie* case of obviousness has been established and submit that the invention is non-obvious in view of the cited references. In order to establish a *prima facie* case of obviousness, there has to be, *inter alia*, some motivation or suggestion provided by the references, or in combination with the knowledge available to the skilled artisan, to modify the art cited or to combine reference teachings. Applicants submit that there is no motivation to combine references and, even if combined, the combination of references does not produce the claimed invention.

As the Examiner points out in the Office Action at page 4, Salvetti et al. do not teach that the rep and cap coding sequences are encoded on an adenovirus vector. Furthermore Salvetti et al., at col. 4, lines 26-27 state that “Preferably, the Rep proteins are expressed under the control of the

AAV p5 and p19 promoters” and at col. 7, lines 27-29 state that the plasmids used may contain the promoters p5, p19 and p40, or any heterologous promoter. The Examiner alleges that Mountz and Zhang, col. 16, lines 52-60 state that expression of rep is attenuated in order to enhance rAAV production. Mountz and Zhang et al. at col. 16, lines 52-54 also state that in the alternative, the cap gene is up-regulated. Furthermore, Mountz and Zhang et al. at col. 2, lines 45-48 indicate that the invention discloses the use of two adenoviruses for large production of rAAV stocks.

The Examiner states at page 5 of the Office Action that it would have been obvious to “substitute the rep and cap plasmid separate from the ad vector taught by Salvetti et al. with the AdAAV vector taught by Mountz and Zhang et al.”. Applicants are confused by the Examiner’s characterization of Salvetti et al. as teaching an “ad vector” when the Examiner previously concluded that Salvetti et al. do not teach that the rep and cap coding sequences are encoded on an adenovirus vector. Applicants believe that there is no motivation or suggestion provided by the two references, or in combination with the knowledge available to the skilled artisan, to modify them or to combine their teachings. Therefore, Applicants contend that no *prima facie* case of obviousness has been made by the Examiner. Even if the two references are combined, one of skill in the art would not arrive at the claimed invention.

Without acquiescing to the rejection and solely in an effort to expedite prosecution, Applicants have cancelled claims 1-3, without prejudice, and have amended claims 4-5, 12, 25-28, and 30-31, thereby obviating this rejection. Applicants request withdrawal of this rejection.

**B.** Claim 11 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Salvetti et al (US 6,509,150) in view of Mountz and Zhang (US 5,589,377) in view of Rabinowitz et al. (US 6,491,907).

Applicants traverse this rejection of claims. Applicants believe that no *prima facie* case of obviousness has been made by the Examiner. Salvetti et al. and Mountz and Zhang are discussed above. Those comments are reiterated here. Furthermore, the Examiner states that neither Mountz and Zhang nor Salvetti et al. teach that the rep and cap sequences are from different serotypes.

Rabinowitz et al. do not cure the deficiencies of Salvetti et al. and Mountz and Zhang. While Applicants disagree with this rejection, without acquiescing to the rejection and solely in an effort to expedite prosecution, Applicants have canceled claims 1-3 without prejudice, and have amended claims 4-5, 12, 25-28, and 30-31, thereby obviating this rejection. Applicants request withdrawal of this rejection.

C. Claim 13 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Salvetti et al. (US 6,509,150) in view of Mountz and Zhang (US 5,589,377) in view of Lebkowski et al. (US 5,589,377).

Applicants traverse this rejection of claims. Applicants believe that no *prima facie* case of obviousness has been made by the Examiner. Salvetti et al. and Mountz and Zhang are discussed above. Those comments are reiterated here. Furthermore, the Examiner states that neither Mountz and Zhang nor Salvetti et al. teach that the rAAV genome is integrated into the chromosome. Lebkowski et al. do not cure the deficiencies of Salvetti et al. and Mountz and Zhang. While Applicants disagree with this rejection, without acquiescing to the rejection and solely in an effort to expedite prosecution, Applicants have canceled claims 1-3, without prejudice, and have amended claims 4-5, 12, 25-28, and 30-31, thereby obviating this rejection. Applicants request withdrawal of this rejection.

D. Claim 31 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Salvetti et al. (US 6,509,150) in view of Mountz and Zhang (US 5,589,377) in view of Synder (US 6,037,177).

Applicants traverse this rejection of claims. Applicants believe that no *prima facie* case of obviousness has been made by the Examiner. Salvetti et al. and Mountz and Zhang are discussed above. Those comments are reiterated here. The Examiner states that neither Mountz and Zhang nor Salvetti et al. teach that rep 78 and 68 are expressed at lower levels than rep 52 and 40. Synder does not cure the deficiencies of Salvetti et al. and Mountz and Zhang. While Applicants disagree with this rejection, without acquiescing to the rejection and solely in an effort to expedite

prosecution, Applicants have canceled claims 1-3, without prejudice, and have amended claims 4-5, 12, 25-28, and 30-31, thereby obviating this rejection. Applicants request withdrawal of this rejection.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 226272007801. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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